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DEPARTMENT OF HEALTH AND HUMAN SERVICE

Food and Drug Administration
New Orleans District
Southeast Region
6600 Plaza Drive, Suite 400
New Orleans, LA 70127

Telephone: 504-253-4519
FAX: 504-253-4520

February 11, 2004

WARNING LETTER NO. 2004-NOL-14

FEDERAL EXPRESS
OVERNIGHT DELIVERY

Mr. Harvey J. Kliebert, Owner
Harvey Kliebert Plant
41067 West Yellow Water Road
Hammond, Louisiana 70403

Dear Mr. Kliebert:

On November 19 - 20, 2003, we inspected your seafood processing facility, located at 41067 West Yellow Water Road, Hammond, Louisiana. We found that you have a serious deviation from the Seafood Hazard Analysis Critical Control Points (HACCP) regulation, Title 21, *Code of Federal Regulations*, Part 123 (21 CFR 123). In accordance with 21 CFR 123.6(g), failure of a processor to have and implement a HACCP plan that complies with this section or otherwise operate in accordance with the requirements of this part, renders the fishery products adulterated within the meaning of Section 402(a)(4) of the Federal Food, Drug, and Cosmetic Act (the Act), 21 U.S.C § 342(a)(4). Accordingly, your frozen, vacuum-packaged alligator meat is adulterated, in that the alligator meat has been prepared, packed, or held under insanitary conditions whereby it may have been rendered injurious to health. You may find the Act and the Seafood HACCP regulations through links in FDA's Internet home page at http://www.fda.gov.

The deviation was as follows:

- You must conduct a hazard analysis to determine whether there are food safety hazards that are reasonably likely to occur and have a HACCP plan that, at a minimum, lists the food safety hazards that are reasonably likely to occur to comply with 21 CFR 123.6(a) and (c)(1). A food safety hazard is defined in 21 CFR 123.3(f) as "any biological, chemical, or physical property that may cause a food to be unsafe for human consumption." However, your firm's HACCP plan for frozen alligator meat does not list the food safety hazard of *Clostridium botulinum* (*C. botulinum*) toxin formation, which is reasonably likely to occur during the expected shelf-life of your product under your present practices.

C. botulinum toxin formation would not be reasonably likely to occur and thus would not need to be included in your HACCP plan if actions such as the following are taken:

a. The product is sealed in packaging material with a final thickness that, at 24°C and one atmosphere of pressure, has an oxygen transmission rate of more than 10,000 cubic centimeters per square meter per 24 hour period of time (10,000 cc/m^2/24hr at 24°C and 1 atm); or,

b. The product is frozen immediately after processing, maintained frozen throughout distribution, and labeled prominently with instructions to hold frozen and to thaw under refrigeration immediately before use (e.g., "Important, Keep Frozen, Thaw Under Refrigeration Immediately Before Use").

c. Alternatively, FDA recognizes the following control as an adequate method of controlling *C. botulinum* in frozen, vacuum-packaged alligator meat, and one that you may wish to consider including in your HACCP plan: the product bears a validated time temperature integrator (TTI), including instructions as to its interpretation, as a monitoring device that is appropriate for control of *C. botulinum* toxin formation on each retail or consumer package. A TTI is a device that provides a clear indication to the retailer/consumer, by color change or other means, that the product may have been exposed to a time and temperature combination that could result in an unsafe product.

We may take further action if you do not correct this violation promptly. For instance, we may take further action to seize your products and/or enjoin your firm from operating.

We are aware that you made a verbal commitment to correct the deviations during the inspection. Please respond in writing within 15 working days from your receipt of this letter. Your response should outline the specific things you are doing to correct these deviations. You should include in your response documentation such as your revised HACCP plan, product labels, or other useful information that would assist us in evaluating your corrections. If you cannot complete all corrections before you respond, we expect that you will explain the reason for your delay and state when you will correct any remaining deviations.

This letter may not list all the deviations at your facility. You are responsible for ensuring that your processing plant operates in compliance with the Act, the Seafood HACCP regulation and the Current Good Manufacturing Practice regulation, 21 CFR 110. You also have a responsibility to use procedures to prevent further violations of the Act and all applicable regulations.

Please send your reply to the U.S. Food and Drug Administration, Attention: Mark W. Rivero, Compliance Officer, at the address above. If you have questions regarding any issue in this letter, please contact Mr. Rivero at (504) 253-4519.

Sincerely,

Patricia K. Schafer
Acting District Director
New Orleans District

Enclosure: Form FDA 483